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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,768	09/22/2003	D. Russell Pflueger	D-3026CON	1359

7590 08/16/2006

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EXAMINER	
SZMAL, BRIAN SCOTT	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,768	PFLUEGER, D. RUSSELL	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102 & 35 USC § 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 30-33 and 36-45 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fox (6,325,806 B1). Fox discloses a material collection system and method and further discloses placing the device into a patient in order to obtain a tissue sample, the device having a cannula having an open distal tip and a rotational element disposed at least partially in the cannula; rotating the rotational element relative to the cannula, thereby drawing tissue into the open distal tip of the cannula; passing the material through the cannula; percutaneously introducing the device such that the distal tip of the cannula is placed in close proximity to the desired sample site; the cannula and rotational element are sized and positioned such that the rotation of the rotational element creates enough suction to

draw the tissue into the distal tip of the cannula; the material is removed without additional suction or aspiration; the rotational element is effective in drawing tissue into the cannula as a substantially single continuous piece; collecting the removed material and observing the removed material; the rotational element includes a distal portion that extends beyond the distal tip of the cannula; the rotational element includes a distal portion that extends a distance in a range of about 0.02-1 inch beyond the distal tip of the cannula; the distal tip is beveled or substantially perpendicular with respect to the longitudinal axis of the cannula; and the collection chamber is structured to facilitate at least one of quantifying the removed material and observing the removed material. See Figures 1, 2, 3a, 3b; Column 11, lines 51-57; and Column 15, lines 26-29.

Even though Fox discloses a device for removing a bone sample, it would have been obvious to one of ordinary skill in the art to utilize the device in a tissue biopsy of the breast, since the operation of the device to obtain the tissue sample would not change regardless of the location of the tissue sample.

4. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox (6,325,806 B1) as applied to claim 30 above, and further in view of Shiber (4,883,458).

Fox, as discussed above, discloses a means of collecting tissue from a site, but fails to disclose the cannula has an outer diameter no larger than about 5mm; and the cannula has an outer diameter no larger than about 2mm.

Shiber discloses an atherectomy system and method and further discloses the cannula has an outer diameter no larger than about 5mm; and the cannula has an outer diameter no larger than about 2mm. See Column 7, lines 11-15.

Since both Fox and Shiber disclose means for removing tissue form the body using an auger-type device, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Fox to include a cannula diameter of no more than 5mm or 2mm, as per the teachings of Shiber, since it would provide a less invasive medical device for obtaining the tissue sample.

Response to Arguments

5. Applicant's arguments filed June 6, 2006 have been fully considered but they are not persuasive.

The Applicants argue Fox fails to disclose the placement of the device in breast tissue and obtaining a breast tissue sample. Fox does primarily disclose the use of a device to obtain a bone tissue sample, but one of ordinary skill in the art would be able to use the device to obtain tissue samples from other parts of the body, including soft tissue samples from a breast. The performance of the device would operate the same in soft tissue (i.e. breast tissue) just as it does in bone when obtaining a bone marrow sample, since bone marrow is a soft tissue.

The Applicants further argue that the cannula of Fox is not placed within the tissue of the patient at the biopsy site. The cannula of Fox is placed against the outer surface of the bone at the biopsy site, but in order to get the cannula to the biopsy site,

the device must be placed within an incision to gain access to the bone. Therefore, the device, and ultimately the cannula, is placed within the tissue at the biopsy site.

6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Fox and Shiber disclose auger-type devices to remove material from a surgical site. The auger action of the device in Shiber acts in the same manner as that of the auger device in Fox, regardless of the different uses of each device.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Thursday, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BS

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